K140112

JUN 06 2014

510(k) Summary

Device Name

Proprietary name: CA 125 II CalSet II

Common name: CA 125 II CalSet II

Classification name: Calibrator, secondary

Establishment Registration

For the CA 125 II CalSet II, the establishment registration number (Roche Diagnostics GmbH Mannheim) is 9610126. The establishment registration number for Roche Diagnostics United States is 1823260.

Classification

The FDA has classified the product as a Class II device.

Panel	Product Code	Classification Name	Regulation Citation
Clinical Chemistry	JIT	Calibrator, Secondary	862.1150

Predicate Device

The CA 125 II CalSet II is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed CA 125 CalSet (k003969).

Device Description

The CA 125 II CalSet II is a lyophilized product consisting of human CA 125 in an equine (Cal 1) and a human (Cal 2) serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Intended Use

CA 125 II CalSet II is used for calibrating the quantitative Elecsys CA 125 II assay on the Elecsys and cobas c immunoassay analyzers.

Reason for Submission

The CA 125 II CalSet II is being changed from a liquid to lyophilized material. In addition, we are decreasing the concentration of Cal 1 to 0 U/mL by using equine serum.

Continued on next page

510(k) Summary

Comparison Table

Table 1 below compares CA 125 II CalSet II with the predicate device, CA 125 II CalSet (k003969).

Changes in the new product include lowering Cal 1 to no CA 125 (by using equine serum), and going from liquid calibrators to lyophilized.

Table 1. Comparison of Candidate and Predicate Devices

Characteristic	CA 125 II CalSet II (Candidate Device)	Elecsys® CA 125 II CalSet (k003969)
Intended Use	CA 125 II CalSet II is used for calibrating the quantitative Elecsys CA 125 II assay on the Elecsys and cobas e immunoassay analyzers.	Same
Format	Lyophilized	Liquid
Analyte	Human CA 125	Same
Matrix	Equine serum (Cal1) and Human serum (Cal 2)	
Levels	Two	Same
Target Ranges	Cal 1: 0 U/mL Cal 2: 500 U/mL	Cal 1: 35 U/mL Cal 2: 500 U/mL
Stability	Lyophilized: • Up until labeled expiration date Reconstituted: • -20°C: 20 weeks (freeze only once) • 2-8248C: 12 weeks • on the Elecsys 2010 and cobas e411 (20-25°C): up to 5 hours • on the MODULAR ANALYTICS E170, cobas e601 and cobas e602 analyzers: use only once	Unopened: • Store at 2-8°C until expiration date Opened: • at 2-8°C: 12 weeks • on the Elecsys 2010 and cobas e411 (20-25°C): up to 5 hours • on the MODULAR ANALYTICS E170, cobas e601 and cobas e602 analyzers: use only once

Continued on next page

Table 1. Comparison of Candidate and Predicate Devices, continued

Characteristic	CA 125 II CalSet II (Candidate Device)	Elecsys® CA 125 II CalSet (k003969)
Handling	Carefully dissolve the contents of one bottle by adding exactly 1.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding foam formation. Transfer the reconstituted calibrators into the supplied empty labeled snap-cap bottles. Elecsys 2010 and **cobas e** 411 analyzers: The reconstituted calibrators should only be left on the analyzers during calibration at 20-25°C. After use, close the bottles as soon as possible and store upright at 2-8°C. Due to possible evaporation effects, not more than 5 calibration procedures per bottle set should be performed. If necessary, freeze in aliquots. MODULAR ANALYTICS, **cobas e** 601 and **cobas e** 602 analyzers: Unless the entire volume is necessary for calibration on the analyzers, transfer aliquots of the reconstituted calibrators into empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Aliquots intended for storage at -20°C should be frozen immediately. Perform **only one** calibration procedure per aliquot.	The calibrators are supplied ready-for-use in bottles compatible with the system. Elecsys 2010 and **cobas e** 411 analyzers: The calibrators should only be left on the analyzers during calibration at 20-25°C. After use, close the bottles as soon as possible and store at 2-8°C. Due to possible evaporation effects, not more than 5 calibration procedures per bottle set should be performed. MODULAR ANALYTICS E170, **cobas e** 601 and **cobas e** 602 analyzers: Unless the entire volume is necessary for calibration on the analyzers, transfer aliquots of the ready-for-use calibrators to empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots at 2-8°C for later use. Perform **only one** calibration procedure per aliquot.

Characteristic	CA 125 II CalSet II (Candidate Device)	Elecsys® CA 125 II CalSet (k003969)
Traceability	The Elecsys CA 125 II assay has been standardized against the Enzymun Test CA 125 II method. This in turn was standardized against the CA 125 II RIA from Fujirebio Diagnostics.	Same
Performance Characteristics	The CA 125 II CalSet II was evaluated for value assignment, stability, and reconstitution.	
Conclusion	The data demonstrate that the performance of the CA 125 II CalSet II is substantially equivalent to that of the predicate device, Elecsys® CA 125 II CalSet.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 6, 2014

ROCHE DIAGNOSTICS
C/O DR. JANE ELLEN PHILLIPS
REGULATORY PROGRAM MANAGER
9115 HAGUE ROAD
INDIANAPOLIS, IN 46250

Re: K140112
Trade/Device Name: CA 125 II CalSet II
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT
Dated: May 16, 2014
Received: May 19, 2014

Dear Dr. Phillips:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140112

Device Name
Elecsys CA 125 II CalSet II

Indications for Use *(Describe)*
CA 125 II CalSet II is used for calibrating the quantitative Elecsys CA 125 II assay on the Elecsys and cobas e immunoassay analyzers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth A. Stafford -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."